• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Due to the following reasons, CMS requested that OMB grant OMB emergency approval of the collection requirements associated with this demonstration Section 641 of the MMA: (1) The statute required that this demonstration begin 90 days after passage of the legislation, which was March 8, 2004; (2) due to the complexities of implementing this demonstration, CMS was unable to meet that deadline; and (3) because of the importance of this demonstration to beneficiaries with serious illnesses and the already delayed time frame, it was urgent that there not be further delays.

Based on the justification referenced above for emergency approval, with OMB concurrence, on May 19, 2004 Volume 69, Number 97, Pages 28894–28895, CMS announced the initiation of procedural requirements set forth in 5 CFR 1320.13 to facilitate compliance with Chapter 25 of Title 44 of United States Code. As the result, the collection requirements associated with this demonstration, ''Application for Participation in Medicare Replacement Drug Demonstration'', were approved under OMB control number 0938–0924.

It should be noted that during the 180-day emergency approval period, CMS will publish a **Federal Register** notice announcing the initiation of an extensive 60-day public comment period on these requirements. Upon completion of the 60-day comment period, we will submit the requirements for OMB review and an extension of this emergency approval.

Authority: Section 641 of the Medicare Prescription Drug Improvement and Modernization Act of 2003.

(Catalog of Federal Domestic Assistance Program No. 93.778 and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 4, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04–14673 Filed 6–24–04; 3:00 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 1976N–0080 and 2000N–1610]

Prescription Drug Products; Digoxin Elixir; Extension to Obtain Marketing Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it will continue to exercise enforcement discretion to assure the continued availability of digoxin elixirs after June 28, 2004, allowing manufacturers to continue to market these products without approved applications until December 28, 2004. FDA is granting this extension to give manufacturers of digoxin elixir additional time to obtain marketing approval and bring products to market.

DATES: The date by which manufacturers must obtain marketing approval is extended to December 28, 2004.

FOR FURTHER INFORMATION CONTACT: Mary E. Catchings, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 26, 2002 (67 FR 42992), FDA published a final rule revoking § 310.500 (21 CFR 310.500), which established conditions for marketing digoxin products for oral use (tablets and elixir). The agency concluded that § 310.500 was no longer necessary because the products, which are new drugs, can be regulated under the approval process for new drug applications and abbreviated new drug applications as set forth in the Federal Food, Drug, and Cosmetic Act (the act). Previously, in the **Federal Register** of November 24, 2000 (65 FR 70573), we reaffirmed the new drug status of oral digoxin products and announced that these products required approved applications for marketing.

The June 26, 2002, final rule advised that manufacturers who were marketing digoxin elixir drug products on or before June 26, 2002, may continue to market their products until June 28, 2004.[1] The final rule stated that a manufacturer who marketed a digoxin elixir drug product without an approved application after that date would be subject to regulatory action.

We permitted this period of continued marketing because we regard digoxin elixir products as medically necessary and, therefore, wanted to allow sufficient time for manufacturers to conduct the required studies and to prepare and submit applications, as well as to allow the agency sufficient time to review these applications. It now appears that as of June 28, 2004, there may not be any manufacturers prepared to market digoxin elixir under an approved application. To assure the continued availability of digoxin elixirs after June 28, 2004, we have decided to extend for 6 months, until December 28, 2004, the date by which manufacturers must obtain marketing approval. This extension will only apply to manufacturers who have submitted applications to FDA and who continue to pursue approval of their applications with due diligence. We will reexamine the need for a continued exercise of enforcement discretion at the end of this 6-month period. In making this determination, we will consider whether there is an approved digoxin elixir product on the market and whether the manufacturer is capable of producing sufficient product to meet patient needs.

This notice is issued under sections 502 and 505 of the act (21 U.S.C. 352, 355)) and under authority delegated to the Associate Commissioner for Policy and Planning (21 CFR 5.20).

Dated: June 24, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–14796 Filed 6–25–04; 2:57 pm]

BILLING CODE 4160–01–S

[1] After June 26, 2002, a new digoxin elixir drug product could not be introduced into the market unless we had approved an application for that product.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0554]

Compliance Policy Guide Regarding Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised Compliance Policy Guide (CPG) Sec. 110.310 entitled ''Prior Notice of Imported Food

Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' The original CPG, which was published in the **Federal Register** of December 15, 2003 (68 FR 69708), provides written guidance to FDA's and Customs and Border Protection's (CBP's) staff on enforcement of section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulations, which require prior notice for all food imported or offered for import into the United States. The CPG has been revised to provide additional guidance to FDA and CBP staff regarding how to address food that is imported or offered for import for noncommercial purposes with a noncommercial shipper. The revised CPG also reflects a change in the date of Stage III enforcement guidance for the interim final rule from May 13, 2004, to June 4, 2004.

DATES: This guidance is final upon the date of publication. However, you may submit written or electronic comments at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Compliance Policy (HFC–230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance may be sent.

Submit written comments on the guidance to the Division of Dockets Management, 5630 Firhers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Domenic Veneziano, Office of Regulatory Affairs (HFC–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 703–621–7809.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of revised CPG Sec. 110.310 entitled ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' This revised guidance is issued with CBP concurrence and explains to FDA and CBP staff the new FDA and CBP policies on enforcement of section 307 of the Bioterrorism Act and its implementing regulations, which require prior notice to FDA of all food imported or offered for import into the United States (68 FR 58974, October 10, 2003 (codified at 21 CFR 1.276 through 1.285)). FDA has revised the original CPG, which was published on December 15, 2003 (68 FR 69708), to include additional guidance regarding food imported or offered for import for noncommercial purposes with a noncommercial shipper. The CPG explains that a ''non-commercial purpose'' generally exists when the food is purchased or otherwise acquired by an individual for nonbusiness purposes and the shipper is the individual (i.e., the individual delivers the food to a post office or common carrier for delivery to self, family member, or friend for nonbusiness purposes, i.e., not for sale, resale, barter, business use, or commercial use). With respect to these food imports, FDA intends to focus its efforts on education through March 2005 (or shortly thereafter, depending on the date of issuance of the final rule). Examples of foods imported or offered for import that may be covered by this noncommercial category include the following:

- Food in household goods, including military, civilian, governmental agency, and diplomatic transfers;
- Food purchased by a traveler and mailed or shipped to the traveler's U.S. address by the traveler;
- Gifts purchased at a commercial establishment and shipped by the purchaser, not the commercial establishment. The revised CPG also corrects the date of Stage III enforcement guidance for the interim final rule from May 13, 2004, to June 4, 2004, per the Automated Broker Interface (ABI) Administrative Message 04–1406 issued by CBP on June 3, 2004.

FDA is issuing this document as level 1 guidance consistent with FDA's good guidance practices regulation § 10.115 (21 CFR 10.115). The revised CPG Sec. 110.310 is being implemented immediately without prior public comment, under § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. Under section 307 of the Bioterrorism Act, the prior notice requirements were effective December 12, 2003, making it urgent that the agencies explain how they intend to enforce those requirements. Moreover, as a result of the revision to the CPG, FDA's policies are generally less burdensome for food imported or offered for import for noncommercial purposes with a noncommercial shipper.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the guidance document. Submit two copies of written comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of this guidance is available on the Internet at *http://www.fda.gov/ora* under ''Compliance References.''

Dated: June 24, 2004.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 04–14766 Filed 6–25–04; 9:17 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Epidemiology Grant Program for American Indians/Alaska Natives; Notice of Competitive Cooperative Agreement Applications

Funding Opportunity Number: HHS–IHS–EPID–2004–0001.

CFDA Number: 93.231.

Dates:

Application Deadline: July 30, 2004.

Application Review: August 16, 2004.

Applicants Notified of Results: On or about September 1, 2004 (approved, recommended for approval but not funded, or disapproved).

Anticipated Award Start Date: September 15, 2004.

I. Funding Opportunity Description

The Indian Health Service (HHS) announces that competitive cooperative agreement applications are now being accepted for the Epidemiology Grant Program for American Indians/Alaska Natives and Urban Indian communities. These cooperative agreements are established under the authority of section 214(a)(1) of the Indian Health Care Improvement Act, Pub. L. 94–437, as amended by Pub. L. 102–573. There will be only one funding cycle during Fiscal Year (FY) 2004. These cooperative agreements will be awarded and administered in accordance with this announcement, Department of Health and Human Service (HHS) at 45